

Contents:

1. **Summary Table 1. Vaccine types:** main issues around the current and future use of existing vaccines and prospects for the pipeline addressing changes in target population.
2. **Summary Table 2. Vaccines licensed or in clinical development:** list of vaccines and issues around their suitability for technical development.

How to use:

- **Vaccine (disease) type:** Each vaccine type has an identification number (e.g., VT001) to enable cross-referencing between the summary tables and the individual directories (available on request).
- **Vaccine:** Each vaccine has an identification number (e.g., V001), which allows cross-referencing between summary tables and the relevant vaccine type directory (available on request).

Methodology:

1. **List of single/combination vaccine (disease) types likely to be important in low- and middle-income countries to 2025:** List of 32 vaccines provided.
2. **For each vaccine type:** search of individual vaccines using public domain information (including the World Health Organization [WHO] and stakeholders) and some internal documents (PATH/GAVI Alliance); attempted to update status using web searching, especially of company websites (including all available press releases); attempted to identify additional vaccines in clinical trials using PubMed and recent reviews.
3. **Criteria for selection:** included vaccines that are licensed in any territory; priority was given to United Nations/WHO prequalified vaccines; focus on vaccines in at least phase I trials for which there is no evidence of the program being abandoned; some vaccines in preclinical stages are listed at the end of directories.

Summary Table 1. Vaccine types that could be used in low- and middle-income countries to 2025: current availability, pipeline, barriers to use, and changes to vaccines that would assist meeting need

Notes:

- Assumption has been made that all future vaccines must be effective and safe, with acceptable reactogenicity.
- Assumed that an ideal vaccine would be inexpensive, easy to administer (including self-administration) via oral/intranasal/skin patch route (but injection acceptable), have small storage volume, storable out of cold chain with long-lasting stability, generate few sharps and minimal clinical waste, and give long-lasting protection after only a single dose; they would be suitable for all ages and safe and effective in the immunosuppressed.

Abbreviations used: **Ab:** antibody; **Al:** aluminum; **BCG:** Bacille Calmette Guerin, for tuberculosis; **CMV:** cytomegalovirus; **conj.:** conjugated (usually polysaccharide conjugated to protein); **CVD:** Centre for Vaccine Development; **D:** diphtheria toxoid (**d:** low-dose; **D:** high-dose); **EPI:** Expanded Programme on Immunization; **ETEC:** enterotoxigenic *E. coli*; **GSK:** GlaxoSmithKline; **HepA:** hepatitis A; **HepB:** hepatitis B; **HepE:** hepatitis E; **Hib:** *Haemophilus influenzae*; **HPV:** human papillomavirus; **ID:** intradermal; **IM:** intramuscular; **IN:** intranasal; **incl.:** including; **IPV:** inactivated polio vaccine; **JE:** Japanese encephalitis; **LMICs:** low- and middle-income countries; **LT:** heat-labile toxin of *E. coli*; **Men:** meningitis, from *Neisseria meningitidis* (serotypes A, C, W135, Y, or X); **MMR:** measles, mumps, and rubella; **mo:** months old; **MR:** measles, rubella; **NA:** not applicable; **NZ:** New Zealand; **OCC:** out of cold chain; **mOPV:** monovalent oral polio vaccine (types 1, 2, or 3); **OPV:** trivalent oral polio vaccine; **P:** pertussis; **PHC:** primary health care; **Pneumo:** pneumococcus, from *Streptococcus pneumoniae*; **PQ:** prequalified; **PS:** polysaccharide (usually implies not conjugated to protein); **RSV:** respiratory syncytial virus; **SAGE:** Strategic Advisory Group of Experts; **SAEs:** serious adverse events; **Sanofi:** Sanofi Pasteur; **STI:** sexually transmitted infection; **T:** tetanus toxoid (or TT); **TB:** tuberculosis; **UK:** United Kingdom; **unconj.:** polysaccharide unconjugated to protein; **VZV:** varicella zoster virus; **WHO:** World Health Organization; **wo:** weeks old; **YF:** yellow fever **yo:** years old.

Disease/ vaccine group (ID number)	Vaccines: licensed/clinical trials	Vaccine delivery strategy		Target population		Issues	Potential for the future
		2008	Desirable	2008	Desirable		
Combination vaccines							
DTP-HepB (VT001)	5 PQ suppliers.	▪ Routine.	▪ Routine.	▪ Infants > 6 wo.	▪ Infants.	▪ Cost. ▪ Whole-cell pertussis is more reactogenic.	▪ Move to acellular pertussis for reduced reactogenicity. ▪ Move to alternative combinations, e.g., with HepB or IPV.
DTP-HepB-Hib (VT002)	Several suppliers: 4 PQ (wP). 2 licensed not PQ. 1 in phase III.	▪ Routine. ▪ Campaign.	▪ Routine. ▪ Campaign.	▪ Routine: infants > 6 wo < 2 yo). ▪ Catch-up for 12–24 mo. ▪ Booster doses < 5 yo.	▪ Expansion of coverage in LMICs.	▪ Cost. ▪ Lack of evidence for burden of Hib. ▪ Whole-cell pertussis is more reactogenic. ▪ Some brands need to	▪ Lower cost. ▪ Move to all liquid. ▪ Move to include IPV. ▪ Move to acellular pertussis.

Landscape analysis: trends in vaccine availability and vaccine delivery technologies
 Summary tables of vaccine types and individual vaccines (licensed and in clinical phase of development)

ANNEX 1

Disease/ vaccine group (ID number)	Vaccines: licensed/clinical trials	Vaccine delivery strategy		Target population		Issues	Potential for the future
		2008	Desirable	2008	Desirable		
						be reconstituted and some are fully liquid. ▪ Combinations without Hib might be more popular.	
DTP-HepB-Hib- IPV (VT003)	2 expensive vaccines used in industrialized countries: 0 PQ. 2 licensed not PQ.	▪ Routine.	▪ Routine, after switch from OPV/mOPV to IPV.	▪ Infants > 6 wo < 2 yo.	▪ Expand coverage, after eradication of polio.	▪ Cost. ▪ Would not be used in countries using OPV/mOPV. ▪ Some brands need to be reconstituted and some are fully liquid.	▪ Lower cost. ▪ Move to replace IPV with Sabin-strain-derived IPV (for safer production).
MenACW135Y-TT (VT006)	No existing vaccine. 4 in phase II. 2 in phase I.	Unknown.	Unknown.	Unknown.	Unknown.	No existing vaccine.	
MR (VT004)	Several vaccines: 2 PQ. 3 licensed not PQ.	▪ Routine. ▪ Campaign.	▪ Routine. ▪ Campaign.	▪ Infants. ▪ Adolescents and preconception females. ▪ Likely contacts of pregnant women.	▪ Same.	▪ Requires reconstitution. ▪ Cost.	▪ Could develop aerosol and/or spray-dried formulations, if aerosol and/or spray-dried measles vaccine is successful.
MMR (VT005)	Several vaccines: 3 PQ. 4 licensed not PQ.	▪ Routine. ▪ Campaign.	▪ Routine. ▪ Campaign.	▪ Infants.	▪ Infants.	▪ Requires reconstitution. ▪ Cost. ▪ Infants not being protected before primary series.	▪ Could develop aerosol and/or spray-dried formulations, if aerosol and/or spray-dried measles vaccine is successful.
DT/dT (VT007)	Several vaccines: DT:4 + dT:3 PQ. DT:3 + dT:6 licensed not PQ.	▪ Routine. ▪ Campaign. ▪ Outbreak response.	▪ Routine. ▪ Campaign. ▪ Outbreak response.	▪ DT: infants < 7 yo (final 2/5 doses). ▪ dT: children > 7 yo (final 2/5 doses) + adults (booster), especially health care workers.	▪ Better coverage.	▪ Tetanus sometimes used on its own because slightly less expensive.	▪ New vaccines that give longer duration by fewer doses with less reactogenicity.
Single vaccines							
Cholera (VT008)	A few suppliers: 1 PQ. 2 licensed not PQ. 3 in phase II/III. 2 in phase I.	▪ Outbreak response. ▪ Some routine.	▪ Routine EPI (in high-risk areas).	▪ Infants > 2 yo.	▪ Infants < 2 yo. ▪ Refugee camp use.	▪ Cost and supply. ▪ Perception of need. ▪ Some brands need to be reconstituted and some are fully liquid.	▪ License for younger infant use. ▪ Single dose. ▪ Longer duration of protection.

Landscape analysis: trends in vaccine availability and vaccine delivery technologies
 Summary tables of vaccine types and individual vaccines (licensed and in clinical phase of development)

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Disease/ vaccine group (ID number)	Vaccines: licensed/clinical trials	Vaccine delivery strategy		Target population		Issues	Potential for the future
		2008	Desirable	2008	Desirable		
							<ul style="list-style-type: none"> ▪ Protect against all serotypes. ▪ Combination with other enteric vaccines. ▪ Use when lack of clean water. ▪ Thermostability would be useful (for stockpile).
CMV (VT009)	No licensed vaccines. 3 in phase II/III. 5 in phase I.	NA.	<ul style="list-style-type: none"> ▪ Routine. ▪ Campaign. 	NA.	<ul style="list-style-type: none"> ▪ Infants (if long-lasting immunity). ▪ Pre-conception women. ▪ Pre-transplant. ▪ Possibly elderly. 	NA.	<ul style="list-style-type: none"> ▪ License for use in infants. ▪ Duration of immunity must protect pregnant women. ▪ Impressive cost-effectiveness data.
Dengue (VT010)	No licensed vaccine. 2 in phase II/III. 2 in phase I.	NA.	<ul style="list-style-type: none"> ▪ Routine. 	NA.	<ul style="list-style-type: none"> ▪ All ages. 	NA.	<ul style="list-style-type: none"> ▪ Need protection against all 4 species. ▪ Protect all ages, especially infants > 6 mo. ▪ Aim for 1–2 doses.
ETEC (VT011)	No licensed vaccine but 3 months of protection with Dukoral. 1 in phase II/III. 1 in phase I.	NA.	<ul style="list-style-type: none"> ▪ Routine. 	NA.	<ul style="list-style-type: none"> ▪ Infants < 5 yo. ▪ Possibly older children. ▪ Possibly adults. 	NA.	<ul style="list-style-type: none"> ▪ License for use in infants. ▪ Preferably from birth. ▪ Protect against diversity of subtypes. ▪ 1–2 doses. ▪ Useful to be combined with other enteric vaccines.
HepA (VT012)	Several vaccines: 8 licensed. 0 in trials.	<ul style="list-style-type: none"> ▪ Routine. ▪ Outbreak response. ▪ Campaign. 	<ul style="list-style-type: none"> ▪ Shift to routine (depends on endemicity). 	<ul style="list-style-type: none"> ▪ Infants > 12 mo. ▪ Adolescents and adults (e.g., travelers). 	<ul style="list-style-type: none"> ▪ Increased coverage of infants of lower age. 	<ul style="list-style-type: none"> ▪ Some brands need to be reconstituted and some are fully liquid. 	<ul style="list-style-type: none"> ▪ Reduce cost. ▪ Promote benefits.
HepB (VT013)	Many monovalent vaccines—2 using Uniject™ device (also used in combinations). Uniject™ device monovalent important for birth dose: 9 PQ. 6 licensed not PQ. 1 in phase II/III. 1 in phase I.	<ul style="list-style-type: none"> ▪ Routine (fixed/outreach). ▪ Campaign. 	<ul style="list-style-type: none"> ▪ More routine at younger ages. ▪ More campaign for catch-up infants and most at-risk adults. 	<ul style="list-style-type: none"> ▪ Infants to prevent perinatal infection. ▪ Infants to prevent any infection. ▪ Adults at higher risk. 	<ul style="list-style-type: none"> ▪ More birth dose where risk of perinatal infection. 	<ul style="list-style-type: none"> ▪ Diminishing market due to proliferation of combination products. 	<ul style="list-style-type: none"> ▪ Reduction in doses could be useful. ▪ Therapeutic vaccines useful for older ages. ▪ Novel adjuvants would probably be required for change from IM to ID. ▪ 1 IN vaccine in phase I (probably for therapeutic use). ▪ Thermostable vaccine possible.

Landscape analysis: trends in vaccine availability and vaccine delivery technologies
 Summary tables of vaccine types and individual vaccines (licensed and in clinical phase of development)

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Disease/ vaccine group (ID number)	Vaccines: licensed/clinical trials	Vaccine delivery strategy		Target population		Issues	Potential for the future
		2008	Desirable	2008	Desirable		
HepE (VT014)	No licensed vaccine. 2 in phase II/III.	NA.	<ul style="list-style-type: none"> Routine. Outbreak response. 	NA.	<ul style="list-style-type: none"> Pregnant women most at risk. Potentially all ages. 	NA.	<ul style="list-style-type: none"> Suitable for emergency use (e.g., after floods). License for all ages but low priority for EPI.
HPV (VT015)	2 very recently available vaccines (2-valent and 4-valent). 2 licensed not PQ. 2 in phase II/III. 1 in phase I.	<ul style="list-style-type: none"> Routine. Campaign. 	<ul style="list-style-type: none"> Routine. Campaign. 	<p>Not yet introduced to LMICs.</p> <ul style="list-style-type: none"> WHO SAGE discussed in November 2008. 	<ul style="list-style-type: none"> In future: routine EPI 0–11 mo (if duration of immunity will protect for long enough); catch-up of women unlikely in some countries. Possibly boys/men (4-valent vaccine). 	<ul style="list-style-type: none"> Cost of first-generation vaccines. Perception of benefits of vaccination in some countries. Cultural issues (STI or anti-cancer vaccine). 	<ul style="list-style-type: none"> Low-cost vaccine. Multi-dose vials. Show immunogenicity in < 10 yo. Protection against most/all strains in LMICs. Reduction in number of doses would be useful (to 2 and/or annual schedule). Female-only: monovalent or with tetanus. For both sexes: could combine with other EPI vaccines. Mercury-free preservative for multi-dose.
Influenza-pandemic (VT016)	Several vaccines available for stockpiling, potentially for pre-pandemic use—but in short supply. 8 licensed not PQ. 15 in phase II/III. 14 in phase I.	<ul style="list-style-type: none"> Pre-pandemic: campaign/routine. 	<ul style="list-style-type: none"> Post-pandemic: outbreak response. Campaign. 	<ul style="list-style-type: none"> Depends on vaccine and nature of strain/disease: infants to elderly; several subgroups to total population. 	<ul style="list-style-type: none"> Protect entire population at risk, those most likely to transmit, most likely to have severe disease, or most essential for services. 	<ul style="list-style-type: none"> Strain of pandemic cannot be predicted in advance. Cost, budget, supply, and logistics. Avian-derived strains tend to be less immunogenic than seasonal and more difficult to manufacture. 	<ul style="list-style-type: none"> Many strategies to improve supply. Novel technologies to improve immunogenicity and ease logistics.
Influenza-seasonal (VT017)	Many suppliers to industrialized: 26 licensed not PQ. 6 in phase II/III. 6 in phase I.	<ul style="list-style-type: none"> Routine (annual, industrialized). 	<ul style="list-style-type: none"> Routine: expand to LMICs (probably annual). 	<ul style="list-style-type: none"> Industrialized: infants, elderly + others at risk of severe disease (or contacts of). 	<ul style="list-style-type: none"> Depends on epidemiology in that country—possibly infants and elderly. 	<ul style="list-style-type: none"> Cost, budget, and supply. Perception of need. Annual change of strains. 	<ul style="list-style-type: none"> Threat of pandemic flu has changed market and rate of innovation.
JE (VT018)	Single-dose vaccine available: 3 licensed not PQ. 4 in phase II/III. 0 in phase I.	<ul style="list-style-type: none"> Routine. Campaign (schools, PHCs). 	<ul style="list-style-type: none"> Routine. Campaign, if new introduction of virus, followed by routine. 	<ul style="list-style-type: none"> EPI: e.g., infants at 8, 9, or 12 mo. At-risk adults. 	<ul style="list-style-type: none"> No changes expected. Expand to new areas as required. 	<ul style="list-style-type: none"> Previous vaccines were less safe. Supply and price. Perception of need. Some brands need to be reconstituted and some are fully liquid. 	<ul style="list-style-type: none"> Single vaccine, but also combined with measles (trials underway). Unlikely to change route of administration. Pan-flavivirus vaccine could be useful, but technical feasibility is unknown.

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		2008	Desirable	2008	Desirable		
Malaria (VT019)	No licensed vaccine; first-generation vaccine in late-stage trials: 5 in phase II/III. 9 in phase I.	NA.	<ul style="list-style-type: none"> ▪ Routine as EPI. ▪ Campaign. 	NA.	<ul style="list-style-type: none"> ▪ Preferably all ages. ▪ Priority: infants and to protect pregnant women. ▪ Travelers, private market. 	NA.	<ul style="list-style-type: none"> ▪ Efficacy (anti-infection or anti-disease) in diversity of transmission settings and against diverse parasites (many strains). ▪ Moderate to long duration of immunity, or short but boostable. ▪ Novel adjuvants probably required for generally poorly immunogenic antigens. ▪ Multi-stage and multi-antigen vaccine probably required, possibly heterologous prime-boost, possibly using live vector.
Measles (VT020)	Several vaccines: 4 PQ. 4 licensed not PQ.	<ul style="list-style-type: none"> ▪ Routine. ▪ Campaign. 	<ul style="list-style-type: none"> ▪ Routine. ▪ Campaign. 	<ul style="list-style-type: none"> ▪ Infants with “second opportunity” as enter primary school. 	<ul style="list-style-type: none"> ▪ Younger infants possibly. 	<ul style="list-style-type: none"> ▪ Logistics and budget. ▪ Some brands need to be reconstituted and some are fully liquid. 	<ul style="list-style-type: none"> ▪ Potential for needle-free and by non-health professionals.
MenA (VT021)	Several unconj. PS vaccines in use (poor immunogenicity), especially for outbreaks in Africa, but being replaced by bi- or multi-valent conj. vaccines (longer duration): 1 licensed not PQ. 1 in phase II/III.	<ul style="list-style-type: none"> ▪ Routine. ▪ Campaign. ▪ Outbreak response. 	<ul style="list-style-type: none"> ▪ Campaign/routine in meningitis belt (with conj. MenA). ▪ More routine, especially in infants. ▪ Better outbreak use, e.g., Africa MenA meningitis belt. 	<ul style="list-style-type: none"> ▪ Campaign: 1 to 29 yo (or most at-risk age groups first), then routine in infants with catch-up every 4 years. 	<ul style="list-style-type: none"> ▪ Preferably all ages, but infants, teenagers, and young adults a priority. 	<ul style="list-style-type: none"> ▪ Supply of low-cost vaccines (multi-valent vaccines are expensive). 	<ul style="list-style-type: none"> ▪ Ideally use conj. multi-valent vaccine (but technical difficulties and cost). ▪ Conj. MenA in late-stage development. ▪ Jet injection possible for campaigns. ▪ Develop OCC version or that is not sensitive to freezing, possibly a non-Al adjuvant. ▪ Prequalified conj. multi-valent vaccine for use in infants < 2 yo. ▪ Develop more-immunogenic and/or with longer duration of protection. ▪ Vaccines suitable for stockpile for outbreak use (MenAC, MenACW135, and MenA conj.).

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Disease/ vaccine group (ID number)	Vaccines: licensed/clinical trials	Vaccine delivery strategy		Target population		Issues	Potential for the future
		2008	Desirable	2008	Desirable		
MenB (VT021)	1 vaccine produced specifically for use in NZ: 1 licensed not PQ (NZ only). 3 in phase II/III.	<ul style="list-style-type: none"> In NZ (epidemic): campaign and routine. 	<ul style="list-style-type: none"> In endemic areas: campaign and routine. 	<ul style="list-style-type: none"> NZ only: long-term epidemic of a particular B strain: protect at-risk age groups. 	<ul style="list-style-type: none"> In NZ: probably continue strategy until epidemic under control. In endemic areas: protect at-risk age groups with either MenB vaccine or multi-valent, incl. MenB, strains. 	<ul style="list-style-type: none"> In NZ: vaccine based on outer membrane vesicles used. 	<ul style="list-style-type: none"> Develop additional MenB vaccines that give long-term protection to all B strain infections (probably as multi-valent vaccines). In medium term, develop multi-valent MenB or broad-spectrum (probably protein-based) MenB vaccine. MenB is less high-priority for use in LMICs compared with MenA and MenCW135 and MenY.
MenC (VT021)	Licensed vaccines are all conj. (to tetanus or diphtheria toxoid) because PS ones can induce tolerance: 3 licensed not PQ. 1 in phase I.					<ul style="list-style-type: none"> MenA has higher priority than MenC in LMICs. Existing conj. vaccines used in western countries (e.g., UK). Some brands need to be reconstituted and some are fully liquid. 	<ul style="list-style-type: none"> Develop multi-valent vaccines containing MenC (e.g., MenAC or MenACW135YX).
MenAC (VT021)	Unconj. MenAC vaccine available at low cost for outbreaks (stockpile): 3 PQ. 3 licensed not PQ. 1 in phase II/III.	<ul style="list-style-type: none"> Outbreak response. 	<ul style="list-style-type: none"> Outbreak response. Routine. 	<ul style="list-style-type: none"> Infants > 2 yo. At-risk age groups, travelers. 	<ul style="list-style-type: none"> Protect all at risk, but probably using vaccine with greater valency (unless price is an issue). 	<ul style="list-style-type: none"> Not conj. so shorter duration. Cost and supply. Some brands need to be reconstituted. 	<ul style="list-style-type: none"> 1 conj. MenAC under development. Multi-valent MenACW135Y(X) vaccines likely to be more useful but also more expensive.
MenBC (VT021)	1 vaccine from Cuba using purified MenB antigen: 1 licensed not PQ.	Unknown.	Unknown.	<ul style="list-style-type: none"> Infants > 3 mo. 	Unknown.	<ul style="list-style-type: none"> Less desirable combination. 	Unknown.
MenACW135 (VT021)	1 unconj. vaccine available for epidemic use in Africa: 1 PQ.	<ul style="list-style-type: none"> Probably outbreak response only. 	Unknown.	<ul style="list-style-type: none"> Epidemics: infants > 2 yo; at-risk adults (e.g., travelers). 	<ul style="list-style-type: none"> Unknown, possibly in younger infants. 	<ul style="list-style-type: none"> Unknown, probably cost and supply. Some brands need to be reconstituted and some are fully liquid. 	<ul style="list-style-type: none"> Conj. version should give longer duration of protection. Might be preferable to add Y (and possibly X) serotype.
MenACW135Y (VT021)	1 unconj. and 1 conj. vaccine (only licensed in > 11 yo): 3 licensed not PQ.			<ul style="list-style-type: none"> Infants > 2 yo (unconj.) or > 11 yo (conj.). 	<ul style="list-style-type: none"> Probably for younger infants. 	<ul style="list-style-type: none"> Probably too costly for LMICs. Unconj. vaccines likely to have short 	<ul style="list-style-type: none"> Existing conj. vaccine has applied for extension of license to > 2 yo. New conj. vaccine (> 2

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		2008	Desirable	2008	Desirable		
	1 in phase II/III.					duration of protection. <ul style="list-style-type: none"> Some brands need to be reconstituted and some are fully liquid. 	mo) in late-stage trial. <ul style="list-style-type: none"> Long duration most useful. Needs to be low cost. Needs to fit into EPI.
Pneumo (VT022)	2 types of multi-valent vaccines: 7-valent conj. and 23-valent unconj; 4 licensed not PQ. 2 in phase II/III.	<ul style="list-style-type: none"> Routine. Individual. 	<ul style="list-style-type: none"> Routine: infants. Individual (to at-risk children and adults, incl. elderly). 	<ul style="list-style-type: none"> Infants. At-risk children, adults, and elderly. 	<ul style="list-style-type: none"> Infants. At-risk children, adults, and elderly. 	<ul style="list-style-type: none"> Cost. Mismatch of 7-valent to serotypes in some LMICs (new conj. vaccines in development will address this issue). Lack of immunogenicity of 23-valent in < 2 yo. 	<ul style="list-style-type: none"> 10- and 13-valent conj. vaccines in late phase III—but probably too costly. IN would be good but IM acceptable. Need better immunogenicity.
Polio—OPV (VT023)	Several suppliers, low cost and oral: 6 PQ. 4 licensed not PQ.	<ul style="list-style-type: none"> Routine. Campaign. 	<ul style="list-style-type: none"> Routine. Campaign. 	<ul style="list-style-type: none"> Infants in endemic areas pre-eradication. 	<ul style="list-style-type: none"> Post-eradication: change to IPV. 	<ul style="list-style-type: none"> Post-eradication: will be considered too risky to use. 	<ul style="list-style-type: none"> Change to IPV and probably mOPV for outbreak response.
Polio—mOPV1 (VT023)	Licensed in several countries—more immunogenic than OPV for the outbreak type: 1 PQ. 2 licensed not PQ.	<ul style="list-style-type: none"> Campaign. Outbreak response. 	<ul style="list-style-type: none"> Campaign. Outbreak response. 	<ul style="list-style-type: none"> Infants. At-risk, during outbreak. 	<ul style="list-style-type: none"> Infants. At-risk, during outbreak. 	<ul style="list-style-type: none"> Type used needs to match outbreak. mOPV2 is not yet licensed. 	<ul style="list-style-type: none"> Post-eradication: probably will be used only for stockpiles for outbreak response.
Polio—mOPV2 (VT023)	Fewer outbreaks with type 2 polio. 1+ in phase II/III.						
Polio—mOPV3 (VT023)	Licensed in several countries—more immunogenic than OPV for the outbreak type: 2 licensed not PQ.						
Polio—IPV (VT023)	Several suppliers, but used only in industrialized countries so far: 1 PQ. 3 licensed not PQ. 1 in phase I (Sabin-IPV).	<ul style="list-style-type: none"> Routine. 	<ul style="list-style-type: none"> Routine (post eradication). 	<ul style="list-style-type: none"> Infants. 	<ul style="list-style-type: none"> Infants. Post-eradication: should replace OPV in EPI. 	<ul style="list-style-type: none"> Cost is greater than 3-valent OPV. Needs to be injected. Combinations with IPV tend to have acellular pertussis, too, which increases cost. 	<ul style="list-style-type: none"> Increasingly incorporated into DTP combinations. Move to manufacture using Sabin attenuated strains for biosafety.

Landscape analysis: trends in vaccine availability and vaccine delivery technologies
 Summary tables of vaccine types and individual vaccines (licensed and in clinical phase of development)

ANNEX 1

Disease/ vaccine group (ID number)	Vaccines: licensed/clinical trials	Vaccine delivery strategy		Target population		Issues	Potential for the future
		2008	Desirable	2008	Desirable		
Rabies (VT025)	Several vaccines: 3 PQ. 6 licensed not PQ.	<ul style="list-style-type: none"> ▪ Individual. 	<ul style="list-style-type: none"> ▪ Routine in high-risk areas. 	<ul style="list-style-type: none"> ▪ Mostly at-risk occupations and post-exposure (especially after dog bites). 	<ul style="list-style-type: none"> ▪ Infants in enzootic areas. 	<ul style="list-style-type: none"> ▪ Cost and supply of cell-culture-derived vaccines. ▪ Preference for post-exposure use and/or passive Ab. ▪ Other control measures (e.g., vaccination of animals and dog control). ▪ Some brands need to be reconstituted and some are fully liquid. ▪ Potential change to ID is associated with regulatory issues over antigen dose and single-dose vials being used for multiple doses (e.g., preservative use). 	<ul style="list-style-type: none"> ▪ Likely that both IM and ID routes will be used, depending on level of endemicity.
Rotavirus (VT026)	2 oral live attenuated vaccines: 2 PQ. 2 in phase II/III. 1 in phase I.	<ul style="list-style-type: none"> ▪ Routine: only after regional efficacy trials (e.g., in Africa and Asia). ▪ Not campaign. 	<ul style="list-style-type: none"> ▪ Routine in EPI; can be with DTP/OPV. ▪ Not catch-up campaign. 	<ul style="list-style-type: none"> ▪ Babies < 24 wo); timing of first dose must be < 12 wo. 	<ul style="list-style-type: none"> ▪ Protect infants under 24 mo: dose close to birth would be useful. 	<ul style="list-style-type: none"> ▪ Very recent. ▪ Cost of existing vaccines. ▪ Existing vaccines are bulky in cold chain. 	<ul style="list-style-type: none"> ▪ Need to repackage existing vaccines. ▪ Liquid easier—or novel, stable oral technology in development. ▪ Lower-cost vaccines in late-stage development. ▪ Increased heat stability: OCC would be very useful. ▪ Improved dosing device could ensure all of dose given. ▪ Second-/third-generation vaccines could be combined with other enteric vaccines.
RSV (VT024)	No existing vaccine (technically challenging): 1 in phase II/III. 2 in phase I.	NA.	<ul style="list-style-type: none"> ▪ Depends on epidemiology and vaccine characteristics; could be routine or campaign. 	NA.	<ul style="list-style-type: none"> ▪ Aim to protect infants from birth (could be via pre-pregnancy vaccination or from birth) and also elderly. 	NA.	<ul style="list-style-type: none"> ▪ Need to establish burden in LMICs. ▪ Vaccine must not cause immunopathology. ▪ If live attenuated, must be non-transmissible. ▪ If IN, must be useable in youngest infants without SAEs.

Landscape analysis: trends in vaccine availability and vaccine delivery technologies
 Summary tables of vaccine types and individual vaccines (licensed and in clinical phase of development)

ANNEX 1

Disease/ vaccine group (ID number)	Vaccines: licensed/clinical trials	Vaccine delivery strategy		Target population		Issues	Potential for the future
		2008	Desirable	2008	Desirable		
Shigella (VT027)	Live attenuated vaccine used only in China (and may be discontinued): 1 licensed not PQ. 3 in phase II/III. 5 in phase I.	NA.	<ul style="list-style-type: none"> Outbreak response (probably as single vaccine). Campaign. 	NA.	<ul style="list-style-type: none"> Infants > 6 mo most at risk. Older age groups. 	NA.	<ul style="list-style-type: none"> Need to protect against many groups/serotypes (multi-valent or broad-spectrum). Could be good as one part of enteric vaccine. Oral probably best, or injected.
Tetanus (VT028)	Several safe and effective vaccines, often in combination: 6 PQ. 6 licensed not PQ.	<ul style="list-style-type: none"> Routine. Campaign. 	<ul style="list-style-type: none"> Routine. Campaign. 	<ul style="list-style-type: none"> All ages, especially pregnant women and neonates and post-injury. 	<ul style="list-style-type: none"> Same; shift to older ages where EPI is effective. 	<ul style="list-style-type: none"> Logistics and budget. Need for multiple doses and boosters throughout life. 	Low-dose dT usually better than TT alone for boosting.
TB (VT029)	Several sources of low-cost BCG; widely used in endemic areas: 4 PQ. 2 licensed not PQ. 7 in phase II/III. 1 in phase I.	<ul style="list-style-type: none"> Routine. 	<ul style="list-style-type: none"> New vaccines: routine, possibly campaign. 	<ul style="list-style-type: none"> Infants, especially birth dose; high-risk adults. 	<ul style="list-style-type: none"> New vaccines: protect infants from birth, protect all ages in endemic areas, prevent reactivation/latency, and HIV+ at particular risk. 	<ul style="list-style-type: none"> Effectiveness of BCG is controversial but still recommended for birth dose in endemic countries (some protection against severe disease in infants). Some brands need to be reconstituted and some are fully liquid. 	<ul style="list-style-type: none"> Need effective vaccines to protect against infection and disease and help treat TB. Several strategies and many in pipeline. Likely to be more than 1 vaccine, and could be used as prime-boost—some could be delivered by oral, IN, or ID routes.
Typhoid (VT030)	2 types of safe, effective, affordable vaccine—usually used single: 5 licensed not PQ. 6 in phase II/III. 3 in phase I.	<ul style="list-style-type: none"> Outbreak response mostly. Campaign. 	<ul style="list-style-type: none"> Underused in areas of highest risk. Not mass vaccination. Could be EPI for infants if suitable vaccine. 	<ul style="list-style-type: none"> School-aged children and adults (but underused). 	<ul style="list-style-type: none"> Infants < 2yo (if vaccine immunogenic in this age group). Immunosuppressed. Travelers. 	<ul style="list-style-type: none"> Not effective in infants < 2 yo. Lack of perception of usefulness in context of other priorities and measures. Some brands need to be reconstituted and some are fully liquid. 	<ul style="list-style-type: none"> Vaccines for use in < 2 yo. More immunogenic with longer duration (conj. or live attenuated). Single-dose vaccines useful. Vaccines that are safe and effective in immunosuppressed.
VZV (VT031)	Several producers of vaccine (increasingly being added to MMR): 6 licensed not PQ. 1 in phase II/III. 1 in phase I.	<ul style="list-style-type: none"> Individual. 	<ul style="list-style-type: none"> As part of EPI, if low-/no cost part of combination vaccine. 	Unknown.	<ul style="list-style-type: none"> Possibly protection of at-risk adults (incl. elderly) in LMICs. For infants: 12–14 mo (potential for eradication). 	<ul style="list-style-type: none"> Low priority for LMICs. Very rare transmission of live attenuated vaccines. Safety issues in immunosuppressed and pregnancy. Some brands need to be reconstituted. 	<ul style="list-style-type: none"> Vaccine safe for use in/contacts of immunosuppressed and pregnant women. Live attenuated vaccines with no transmission.

Disease/ vaccine group (ID number)	Vaccines: licensed/clinical trials	Vaccine delivery strategy		Target population		Issues	Potential for the future
		2008	Desirable	2008	Desirable		
YF (VT032)	Several vaccines: 3 PQ. 2 licensed not PQ.	<ul style="list-style-type: none"> Outbreak control. Campaign then routine. 	<ul style="list-style-type: none"> In EPI in only some countries. Aim for EPI dosing alongside measles (in endemic areas). 	<ul style="list-style-type: none"> EPI: infants at 9 mo. 	Unknown.	<ul style="list-style-type: none"> Supply (but WHO stockpile for outbreaks). YF cannot be given within 3 weeks of parenteral cholera but fine with oral cholera vaccine. Some brands need to be reconstituted. 	<ul style="list-style-type: none"> Safer live attenuated, incl. recombinant YF as vector for other vaccines. Vaccines with reduced SAEs. Change to ID (likely to always be injected vaccines). Could be part of pan-flavivirus vaccine. Vaccine that can be given alongside cholera would be useful.

Summary Table 2. Vaccines

Notes:

- **Availability:** based only on whether the vaccine is licensed in any territory and what stage of clinical trial.
 - **2008:** currently licensed in any territory, some are also United Nations/WHO prequalified.
 - **2015:** assigned to vaccine candidates undergoing phase II or phase III trials in 2008.
 - **2025:** assigned to vaccine candidates undergoing phase I trials in 2008.
- **Presentation, storage, and immunization route:**
 - Generally not known for future vaccines. The most likely presentation and storage conditions are given.
- **Potential presentation and delivery:** predictions have been made on existing knowledge and the following assumptions.
 - Vaccines currently delivered subcutaneously or intramuscularly could be suitable for intradermal delivery (microneedles or jet injector); however, lack of reactogenicity of adjuvant delivered by this route would need to be demonstrated.
 - Liquid, non-live vaccines without adjuvants or with aluminum-salt-based adjuvants (but not other types of adjuvants) are likely to be compatible with PATH freeze-protection technology.
 - Non-live vaccines without adjuvants or with aluminum-salt-based adjuvants (but not other types of adjuvants) are likely to be compatible with spray-drying.
- **Numbers:**
 - VT000: Identification number to cross-reference with vaccine type directories.
 - V000: Identification number to cross-reference within relevant vaccine type directory.

Abbreviations used: **Ab:** antibody; **Ad5:** adenovirus type 5; **Ad35:** adenovirus type 35; **ADT:** adult diphtheria toxoid, tetanus toxoid; **Al:** aluminum; **AMA1:** apical membrane antigen 1; **AMA1-C1:** apical membrane antigen 1 (multi-allelic mixture); **aP:** acellular pertussis vaccine; **AS:** adjuvant system (01, 02, 02A, 03, and 04 [proprietary to GlaxoSmithKline]); **BB-NCIPD:** Bul Bio National Center of Infectious and Parasitic Diseases; **BCG:** Bacille Calmette Guerin, for tuberculosis; **BPRC:** Biomedical Primate Research Centre, The Netherlands; **CIGB:** Centre for Genetic Engineering and Biotechnology, Cuba; **CMV:** cytomegalovirus; **conj.:** conjugated (usually polysaccharide conjugated to protein); **CRM197:** mutated diphtheria toxin; **D:** diphtheria toxoid (**d:** low-dose; **D:** high-dose); **EBA-175 RII-NG:** *Plasmodium falciparum* erythrocyte-binding antigen 175 kDa Region II-nonglycosylated; **EPI:** Expanded Programme on Immunization; **ETEC:** enterotoxigenic *E. coli*; **F, G, and M:** fusion, glycoprotein, and matrix proteins of respiratory syncytial virus; **GSK:** GlaxoSmithKline; **HA:** hemagglutinin; **HepA:** hepatitis A; **HepB:** hepatitis B; **HepE:** hepatitis E; **HEV:** hepatitis E virus; **Hib:** *Haemophilus influenzae*; **HPV:** human papillomavirus; **ID:** intradermal; **IM:** intramuscular; **IN:** intranasal; **incl.:** including; **IP:** inactivated poliomyelitis; **IPV:** inactivated polio vaccine; **IS:** immune stimulating; **JE:** Japanese encephalitis; **JPRI:** Japan Poliomyelitis Research Institute; **LPS:** lipopolysaccharide (usually implies not conjugated to protein); **MDCK:** Madin-Darby canine kidney cells; **Men:** meningitis, from *Neisseria meningitidis* (serotypes A, C, W135, Y, or X); **MMR:** measles, mumps, and rubella; **mo:** months old; **MPL-Al:** monophosphoryl lipid A plus aluminum hydroxide; **MPL-QS-21:** monophosphoryl lipid A plus QS21; **MR:** measles, rubella; **MVA:** modified vaccinia Ankara; **MVI:** Malaria Vaccine Initiative; **MVP:** Meningitis Vaccine Program; **NICHD:** National Institute of Child Health and Human Development; **NIAID:** National Institute of Allergy and Infectious Disease; **NIH:** US National Institutes of Health; **NZ:** New Zealand; **mOPV:** monovalent oral polio vaccine (types 1, 2, or 3); **OPV:** trivalent oral polio vaccine; **P:** pertussis; **PHC:** primary health care; **Pneumo:** pneumococcus, from *Streptococcus*

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 Summary tables of vaccine types and individual vaccines (licensed and in clinical phase of development)

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pneumoniae; **PPV**: pre-pandemic vaccine; **PQ**: prequalified; **PS**: polysaccharide; **PSV**: pandemic-specific vaccine; **rEPA**: recombinant *Pseudomonas aeruginosa* exotoxin A protein; **RSV**: respiratory syncytial virus; **SAEs**: serious adverse events; **Sanofi**: Sanofi Pasteur; **STI**: sexually transmitted infection; **T**: tetanus toxoid (or **TT**); **TB**: tuberculosis; **unconj.**: polysaccharide unconjugated to protein; **VLP**: virus-like particle; **VZV**: varicella zoster virus; **WHO**: World Health Organization; **wo**: weeks old; **WRAIR**: Walter Reed Army Institute of Research; **YF**: yellow fever; **yo**: years old.

Availability: 2008 2015 2025			Existing/2008: Formulation Presentation Storage Route				Notes on potential presentation and delivery	
DTP-HepB (VT001)								
DTP-HB PQ (Bio Farma; V233)			Protein, probably with Al adjuvant.	Liquid, 5-, 10-dose vial.	Freeze sensitive; store 2–8°C.	IM.	<ul style="list-style-type: none"> • All formulations are likely to be compatible with PATH's freeze-protection technology or spray-drying. • ID delivery may be possible, provided there are no reactogenicity problems with Al adjuvants. 	
Zilbrix PQ (GSK; V305)			Protein + Al adjuvant.	Liquid, 1-, 2-, 10-dose vial.	Unknown.	Unknown.		
Titanrix-HepB PQ (GSK; V34)				Liquid, 1-, 2-, 10-dose vial.	Freeze sensitive; store 2–8°C.	IM.		
Ecovac4 PQ (Panacea; V235)				Liquid; 1-dose; Uniject™ device or multi-dose vial.				
Sii-Q-Vac PQ (Serum Institute of India; V236)			Protein, probably with Al adjuvant.	Liquid, 1-, 10-dose vial.				
Shantetra PQ (Shantha; V237)			Protein + Al adjuvant.	Liquid, multi-dose vial.				
DTP-HepB-Hib (VT002)								
Quinvaxem PQ (Berna/Novartis; V238)			Protein (incl. wP) + conj. Hib PS (to CRM197) + Al adjuvant.	Liquid, 1-dose vial.	Freeze sensitive; store 2–8°C.	IM.	<ul style="list-style-type: none"> • All formulations are likely to be suitable for spray-drying. • PATH freeze-protection technology applies. 	
Easy Five PQ (Panacea; V239)			Protein (incl. wP) + conj. Hib PS (to CRM197) + Al adjuvant.					
PQ (Shantha; V325)			Unknown.	Unknown.	Unknown.	Unknown.		
Titanrix-HepB-Hib PQ (GSK; V306)			Protein (incl. wP) + conj. Hib PS (to TT) + Al adjuvant.	Liquid, 1, 2, and 10 doses per vial.	Unknown.	Unknown.		
Zilbrix-Hib PQ (GSK; V307)				Liquid, 1 and 2 doses per vial.	Unknown.	Unknown.		
	UNIFIVE (Sanofi; V240)		Probably protein (incl. aP) + conj. Hib PS + Al adjuvant.	Probably liquid.	Probably freeze sensitive; store 2–8°C.	Probably IM.		

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Availability: 2008 2015 2025			Existing/2008: Formulation Presentation Storage Route				Notes on potential presentation and delivery		
DTP-HepB-Hib-IPV (VT003)									
Hexavac (Sanofi; V242)		3-valent killed virus (IPV), protein (incl. aP) + conj. Hib PS (to TT) + Al adjuvant.	Liquid, 1-dose prefilled syringe.	Freeze sensitive; store 2–8°C.	IM.	<ul style="list-style-type: none"> All formulations are likely to be suitable for spray-drying. Not known whether PATH freeze-protection technology will be compatible with PS vaccines. Hexavac only: market authorization suspended 2005—low responses to HepB—indicative of immune interference. 			
Infanrix hexa (GSK; V243)			Liquid (DTP-HepB-IPV), 1-dose prefilled syringe used to reconstitute lyophilized Hib in 1-dose vial.						
MenACW135Y-TT (VT006)									
	MenACWY-TT (GSK; V199)	▪ PS conj. to tetanus, probably Al adjuvant.	Unknown.	Unknown.	▪ Probably IM.	<ul style="list-style-type: none"> Not known whether PATH freeze-protection technology will be compatible with PS vaccines. Spray-drying likely to be applicable. 			
MMR (VT005)									
M-M-RVaxPro PQ (Sanofi; V170)		Live attenuated.	Lyophilized, 1- or 10-dose vial or prefilled syringe + diluent.	Diluent is freeze sensitive; store 2–8°C; virus is light sensitive.	SC.	<ul style="list-style-type: none"> The lyophilized formulations have the potential to be delivered by aerosol/inhalation following reconstitution. Dry-powder thermostable formulations may be feasible, but possibly technically difficult to develop. Use of reconstitution devices could be advantageous. 			
MMR Priorix PQ (GSK; V171)			Lyophilized, 1-dose vial or prefilled syringe of diluent for reconstitution.		SC/IM.				
Tresivac PQ (Serum Institute of India; V172)			Lyophilized; 1-, 2-, 5-, or 10-dose vial diluent.		SC.				
Measles, mumps, and rubella vaccine (China National; V173)			Lyophilized, 1-dose vial.	Store 2–8°C; virus is light sensitive.	SC.				
Abhay-Vac 3 (Indian Immunologicals; V174)			Lyophilized, 1- or 5-dose vial.	Diluent is probably freeze sensitive; store 2–8°C; virus is light sensitive.	Probably SC.				
(Intervax; V175)			Lyophilized; 1-, 5-, or 10-dose vial + diluent.	Probably diluent is freeze sensitive; store 2–8°C;	SC/IM.				

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Availability: 2008	2015	2025	Formulation	Presentation	Existing/2008: Storage	Route	Notes on potential presentation and delivery
					virus is light sensitive.		
M-M-RVAXPRO (Merck; V176)				Lyophilized, 1-dose vial + diluent.	Diluent is freeze sensitive; store 2–8°C; virus is light sensitive.		
MR (VT004)							
MoRu-Viraten PQ (Berna; V164)			Live attenuated.	Lyophilized.	Unknown.	SC.	<ul style="list-style-type: none"> The lyophilized formulations have the potential to be delivered by aerosol/inhalation following reconstitution. Dry-powder thermostable formulations may be feasible, but possibly technically difficult to develop. Use of reconstitution devices could be advantageous.
Measles and rubella PQ (Serum Institute of India; V165)				Lyophilized; 1-, 2-, 5-, or 10-dose vial + diluent.	Diluent is freeze sensitive; store 2–8°C; virus is light sensitive.		
MR Vax II (Merck; V166)				Lyophilized.	Store 2–8°C.		
Intervax; V167)				Lyophilized; 1-, 5-, or 10-dose vial + diluent.	Unknown.	Probably SC.	
Measles and rubella vaccine, live (China National; V168)				Lyophilized, 1-dose vial.	Store < 8°C; virus is light sensitive.	SC.	
DT/dT (VT007)							
DT PQ, Tetadif (dT) PQ (BB-NCIPD; V189)			Toxoids, Al adjuvant.	Liquid, 1-dose ampoule and 10- or 20-dose vial.	Freeze sensitive; store 2–8°C.	DT: SC/IM. dT: IM.	<ul style="list-style-type: none"> All formulations are likely to be compatible with PATH's freeze-protection technology or spray-drying. ID delivery may be possible, provided there are no reactogenicity problems with Al adjuvants.
DT PQ, DECAVAC (dT) PQ (Sanofi; V190)				Liquid; DT: 1-dose vial, dT: 1-dose vial, or a prefilled syringe.		Probably IM.	
Sii Dual Antigen (DT) PQ, dT PQ (Serum Institute of India; V191)				Liquid; DT/dT: 1-, 10-, or 20-dose vial.		IM.	
DT PQ (Bio Farma; V194)				Liquid, 10-dose vial.		SC/IM.	
DT (Haffkine; V192)				Liquid, 10- or 20-dose vial.		IM.	
ADT booster (dT) (CSL; V193)				Liquid, 1-dose prefilled syringe.			

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Availability: 2008 2015 2025			Existing/2008: Formulation Presentation Storage Route				Notes on potential presentation and delivery
Ditanrix Paedriatrix (DT) (GSK; V308)			Toxoids, Al adjuvant.	Liquid, 1-dose vial or prefilled syringe.	Freeze sensitive; store 2–8°C.	Unknown.	<ul style="list-style-type: none"> Live and killed formulations are unlikely to be suitable for the PATH freeze technology. Spray-drying is likely to be possible for the killed vaccines and may be possible for the live attenuated formulations. Sugar-glass stabilization has been demonstrated with Cholergarde®. Use of reconstitution devices could be advantageous.
dT (Novartis; V195)			Toxoids, Al adjuvant.	Probably liquid.	Probably freeze sensitive; store 2–8°C.	Probably IM.	
dT (Birmex; V196)			Toxoids, Al adjuvant.	Liquid, 10-dose vial.	Probably freeze sensitive; store 2–8°C.		
VA DIFTET (DT) (Finlay; V197)			Toxoids, probably Al adjuvant.	Probably liquid, 1-dose vial.			
Cholera (VT008)							
Dukoral PQ (SBL Vaccin/Crucell; V035)			4-valent, killed.	Liquid + stomach buffer.	Freeze sensitive; store 2–8°C.	Oral. Unknown.	<ul style="list-style-type: none"> Live and killed formulations are unlikely to be suitable for the PATH freeze technology. Spray-drying is likely to be possible for the killed vaccines and may be possible for the live attenuated formulations. Sugar-glass stabilization has been demonstrated with Cholergarde®. Use of reconstitution devices could be advantageous.
ORC-Vax (Vabiotech; V036)			2-valent, killed.	Liquid; no adjuvant, no buffer.	Freeze sensitive; store 2–8°C.		
Orochol Berna® (Berna/Crucell; V037)			Live attenuated.	Lyophilized, double-chamber Al foil sachet with buffer.			
	CholeraGarde® (Avant; V038)		Live attenuated.	Lyophilized.			
	reformulated ORC-Vax (Shantha; V040)		2-valent, killed.	Liquid.			
	Vibrio cholerae 638 (Finlay; V041)		Live attenuated.	Liquid.			
	Peru-15pCTB (Avant; V039)		Live attenuated.	Unknown.			
		reformulated ORC-Vax (Bio Farma; V042)	2-valent, killed.	Probably liquid.			
CMV (VT009)							
	Towne (Vical; V053)		Live attenuated.	Not known.	Not known.	SC.	<ul style="list-style-type: none"> Vaccines in early stage of development, so likely formulations are uncertain. DNA vaccines are likely to be suitable for ID delivery. Protein formulations may be suitable for ID delivery if adjuvants are not reactogenic.
	gB/MF59 (Sanofi; V054)		Protein + MF59 adjuvant.	Probably liquid.	2–8°C likely.	Probably IM.	
	CMV glycoprotein B (NIAID/Royal Free; V056)		Protein.				
		VCL-CB01 (Vical; V052)	DNA.	Not known.			

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 Summary tables of vaccine types and individual vaccines (licensed and in clinical phase of development)

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Availability:			Existing/2008:				Notes on potential presentation and delivery		
2008	2015	2025	Formulation	Presentation	Storage	Route			
		ALVAC-CMVgB (Sanofi; V055)	Live attenuated.	Unknown.	Unknown.				
		VCL-CT02 (Vical; V057)	DNA + CRL1005 adjuvant + benzalkonium chloride.						
		VEE VRPs (Alphavax; V058)	DNA as VLPs.						
		(GSK; V076)	Protein + GSK adjuvant.						
Dengue (VT010)									
	ChimeriVax Tetravalent (Acambis; V013)		Live attenuated.	Probably lyophilized.	Probably similar to YF vaccine: 2-8°C.	SC.	<ul style="list-style-type: none"> Use of reconstitution devices could be advantageous. Spray-drying might be possible, but has not been demonstrated. 		
	(GSK; V014)			Unknown.	Unknown				
		(NIH; V015) Expect: 2014				Unknown.			
		DENVax (Inviragen; V016)							
ETEC (VT011)									
	LT patch (Iomai; V135)		Toxoid.	Patch.	Possibly stored at room temp.	Dermal patch.	<ul style="list-style-type: none"> Dukoral, oral cholera vaccine, is indicated for ETEC in all countries of registration. For example the European Union and Australia. LT patch is the lead (and possibly only suitable) application for TCI delivery (Iomai). Ongoing PATH project to develop thermostable formulation. 		
			Live attenuated.	Probably liquid.		Oral.			
HepA (VT012)									
Vaqta (Merck; V079)			Killed + Al adjuvant.	Liquid, 1-dose prefilled syringe.	Freeze sensitive; store 2-8°C.	IM.	<ul style="list-style-type: none"> PATH freeze-prevention technology or spray-drying are likely to be applicable to all formulations except Expaxal (virosomes) and HaVac (live attenuated). ID delivery may be possible (for virosomal vaccines, not Al-adjuvanted, which is the majority); reactogenicity studies are required. 		
Expaxal (Berna/Crucell; V080)			Killed, adsorbed onto virosomes.	Emulsion, 1-dose prefilled syringe.					
Havrix (GSK; V081)			Killed + Al adjuvant.	Liquid, 1-dose prefilled syringe/1-dose vial.					
Avaxim (Sanofi; V082)				Liquid, 1-dose prefilled syringe.					

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Availability: 2008 2015 2025			Formulation	Existing/2008: Presentation Storage Route			Notes on potential presentation and delivery
HAVAX (Vabiotech; V083)				Liquid.			
HAVpur (Novartis; V084)			Killed, adsorbed onto virosomes.	Emulsion, 1-dose prefilled syringe.			
Healive® (Sinovac; V085)			Killed + adjuvant (probably Al).	Liquid, 1-dose prefilled syringe.			
HaVac (China National; V146)			Live attenuated.	Lyophilized.	Store < 8°C.	SC.	
HepB (VT013)							
Engerix PQ (GSK; V086)			Protein + Al adjuvant.	Liquid, 1-dose, prefilled syringe.	Freeze sensitive; store 2–8°C.	IM.	<ul style="list-style-type: none"> PATH freeze-prevention technology or spray-drying are likely to be applicable to all formulations.
Hepavax-Gene® PQ (Green Cross; V088)			Protein probably with Al adjuvant.	Probably liquid.	Probably freeze sensitive; store 2–8°C.	Probably IM.	<ul style="list-style-type: none"> PATH is reformulating a HepB vaccine for heat and freeze stability using Arecor and PATH technology, in collaboration with a vaccine producer.
Hepatitis B Uniject™ PQ (Bio Farma; V089)			Protein probably with Al adjuvant.	Probably liquid; in Uniject™ device.			<ul style="list-style-type: none"> ID delivery may be possible depending on adjuvant reactogenicity.
Euvax-B PQ (LG Life Sciences; V090)			Protein + Al adjuvant.	Liquid.	Freeze sensitive; store 2–8°C.	IM.	<ul style="list-style-type: none"> Adjuvant in Heplisav may influence which stabilizing technologies can be used.
Recombivax HB® (Merck; V091)				Liquid, vial or prefilled syringe.			
Enivac HB also Enivac Safsy (Uniject™) PQ (Panacea; V092)				Liquid, multi-dose vial or Uniject™ device.	Freeze sensitive; store 2–8°C; short periods at 25–30°C not a problem.		
Gene Vac-B® PQ (Serum Institute of India; V093)				Liquid, 1- or 10-dose vial.	Probably freeze sensitive; store 2–8°C.		
Shanvac™-B PQ (Shantha; V094)				Liquid, 1- or 10-dose vial or Uniject™ device.	Freeze sensitive; store 2–8°C.		
Heberbiovac HB PQ (CIGB; V099)			Protein probably with Al adjuvant.	Probably liquid.	Probably freeze sensitive; store 2–8°C.	Probably IM.	

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Availability:			Existing/2008:				Notes on potential presentation and delivery
2008	2015	2025	Formulation	Presentation	Storage	Route	
Fendrix (GSK; V087)			Protein + AS04 adjuvant (MPL-Al).	Liquid, prefilled syringe.	Freeze sensitive; store 2–8°C.	IM.	
HBvaxPRO (Sanofi; V095)			Protein + Al adjuvant.	Liquid, 1-dose vial.			
r-HBvax (Vabiotech; V096)			Protein probably with Al adjuvant.	Liquid, 1- or multi-dose vial.			
Revac-B+™ (Bharat; V097)							
Elovac-B® (Indian Immunologicals; V098)							
TEMREVAC-HB (China National; V011)			Protein probably with adjuvant.	Unknown.			
	HEPLISAV™ (Dynavax; V101)		Protein + novel TLR-agonist as adjuvant.	Probably liquid.	Unknown.	Probably IM.	
		NASVAC (CIGB; V100)	Protein, no adjuvant.	Liquid, in Accuspray.		IN.	
HepE (VT014)							
	rHepE (GSK; V077)		Protein + Al adjuvant.	Liquid.	Unknown.	IM.	▪ PATH freeze-prevention technology or spray-drying are likely to be applicable.
	HEV 239 (Xiamen; V078) Possibly approved by 2011.			Probably liquid.		Probably IM.	
HPV (VT015)							
Gardasil (Merck; V001)			4-valent protein, as VLPs + Al adjuvant	Liquid, 1-dose vial or prefilled syringe.	Freeze sensitive; store 2–8°C.	IM.	▪ All formulations are likely to be compatible with PATH's freeze-protection technology or spray-drying.
Cervarix (GSK; V002)			2-valent protein, as VLPs + AS04 (MPL/Al) adjuvant.				
	Bivalent HPV vaccine (Xiamen; V003)		2-valent protein, as VLPs + Al adjuvant.	Liquid.	Unknown.		
	Quadrivalent HPV vaccine (Xiamen; V004)		4-valent protein, as VLPs + Al adjuvant.	Probably liquid.		Probably IM.	
	Octovalent HPV (Merck; V063)		8-valent protein, as VLPs probably + adjuvant.	Unknown.			

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Availability: 2008 2015 2025	Formulation	Existing/2008: Presentation	Storage	Route	Notes on potential presentation and delivery
Influenza-pandemic—H5N1 (VT016) PPV, PSV					
(Biken; V268)	Whole virion, Al adjuvant.	Probably liquid.	Probably freeze sensitive; store 2–8°C.	Probably IM.	<ul style="list-style-type: none"> Vaccines likely to be stockpiled (unlike seasonal influenza vaccines); therefore, stability is important. Freeze-protection/thermostability technologies and route of delivery are likely to be dependent on adjuvant used.
Pandemrix —PSV (GSK; V269)	Split, AS03 adjuvant.	Liquid (antigen) + emulsion (adjuvant) for mixing to form 10 doses.	Freeze sensitive; store 2–8°C.	IM.	
Prepandrix —PPV (GSK; V270)					
Daronrix —PSV mock-up vaccine (GSK; V271)	Whole virion, Al adjuvant.	Liquid; prefilled syringe or a 1-, 10-, or 20-dose vial.	Freeze sensitive; store 2–8°C.		
(Kitasako; V272)	Whole virion, Al adjuvant.	Unknown.	Unknown.	Probably IM.	
Focetria —PSV, Afunov —PPV (Novartis; V273)	Surface antigen, MF59 adjuvant.	Liquid, prefilled syringe or a 1- or 10-dose vial.	Freeze sensitive; store 2–8°C.	IM.	
PSV (Sanofi; V274)	Split, no adjuvant.	Liquid, 5-dose vial.	Freeze sensitive; store 2–8°C.	IM.	
PanFlu (Sinovac; V275)	Whole virion,	Unknown.	Unknown.	Probably injected.	
Celvapan —PSV (to make a PPV too) (Baxter; V276)	Whole virion (manufactured in Vero cells).	Probably 10-dose vial.	Unknown.		
PanVax CSL 401 —PSV (CSL; V277)	Split, Al-based adjuvant.	Unknown.	Unknown.		
	(Denka Seiken; V278)	Whole virion, Al adjuvant.	Unknown.		
	(Iomai; V279)	“Pandemic flu vaccine” + IS patch.	Unknown.		
	(Kaketsuken; V280)	Whole virion, Al adjuvant.	Unknown.		
	(Nobilon; V284)	Whole virion, Al adjuvant.	Unknown.		
	(Novavax/Bill & Melinda Gates Foundation; V285)	VLPs from baculovirus, no adjuvant.	Unknown.		
	Emerflu (Sanofi; V288)	Split, Al-based adjuvant.	Liquid.	Freeze sensitive; store 2–8°C.	
					IM.

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Availability: 2008 2015		Existing/2008: Formulation Presentation Storage Route				Notes on potential presentation and delivery
2025						
	(Sanofi; V326)	Split, low-antigen dose, "new adjuvant."	Liquid.	Freeze sensitive; store 2–8°C.	IM.	
	(Sinovac; V289)	Split.	Unknown.	Unknown.	Probably injected.	
	(Antigen Express; V312)	Chemically synthesized peptides.	Unknown.	Unknown.	Probably injected.	
	(Avir Green Hills; V313)	Live attenuated.	Unknown.	Unknown.	Probably IN.	
	GelVac (DelSite; V314)	Inactivated.	Unknown.	Unknown.	IN.	
	(MedImmune; V281)	Live attenuated.	Unknown.	Unknown.	IN.	
	Omniflu (Microgen; V282)	Subunit, version with polyoxidonium adjuvant.	Unknown.	Unknown.	Probably injected.	
	(NIH; V283)	DNA vaccine.	Unknown.	Unknown.	Probably injected.	
	(Omnivest; V286)	Whole virion.	Unknown.	Unknown.	Probably injected.	
	(PowderMed; V315)	DNA.	Unknown.	Unknown.	Gene gun.	
	Pandemic Flublok (Protein Sciences; V287)	Recombinant HA from baculovirus ± AI-based adjuvant.	Unknown.	Unknown.	Probably injected.	
	(Solvay; V290)	Subunit, AI-based adjuvant (version manufactured in MDCK).	Unknown.	Unknown.	Probably injected.	
	(Vaxin; V316)	Adenovirus.	Unknown.	Unknown.	IN.	
	(Vaxinnate; V317)	Protein with HA and flagellin.	Unknown.	Unknown.	Unknown.	
	(Vical; V318)	DNA + Vaxfectin adjuvant.	Unknown.	Unknown.	Probably injected.	
Influenza-pandemic—H5N2 (VT016)						
	(Microgen; V293)	Live attenuated.	Unknown.	Unknown.	Probably IN.	

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Influenza-pandemic—H5N3 (VT016)										
		(Novartis; V294)	Subunit, MF59 adjuvant.	Unknown.	Unknown.	Probably injected.				
Influenza-pandemic—H7N3 (VT016)										
		(NIAID; V319)	Unknown.	Unknown.	Unknown.	Unknown.				
Influenza-pandemic—H9N2 (VT016)										
	(Crucell/Berna; V296)		Whole virion, Al adjuvant.	Unknown.	Unknown.	Probably injected.				
	(Crucell/Berna; V302)		Virosomal, no adjuvant.	Unknown.	Unknown.	Probably injected.				
	(Novartis; V298)		Surface antigen, MF59 adjuvant.	Unknown.	Unknown.	Probably injected.				
		(Novavax; V299)	Live attenuated.	Probably liquid.	Unknown.	Probably IN.				
		(MedImmune; V303)	Live attenuated, no adjuvant.	Unknown.	Unknown.	IN.				
Influenza-pandemic—trivalent: H5N3, H3N2, B (VT016)										
		(Novartis; V300)	Subunit.	Unknown.	Unknown.	Probably injected.				
Influenza-pandemic—“Universal” (VT016)										
	ACAM-FLU (Sanofi/Acambis; V320)		Protein plus adjuvant.	Unknown.	Unknown.	Unknown.				
	(BiondVax; V321)		Protein.	Unknown.	Unknown.	Unknown.				
	CYT015-M2AP (Cytos; V322)		VLPs.	Unknown.	Unknown.	Possibly IN.				
	(Jenner Institute; V323)		MVA.	Unknown.	Unknown.	Unknown.				
	(Merck; V301)		Recombinant M2 antigen.	Unknown.	Unknown.	Probably injected.				
	Flagellin. AvM2e (Vaxinna; V324)		Protein fused to flagellin.	Unknown.	Unknown.	Unknown.				
Influenza-seasonal (VT017)										
Inflexal V (Berna; V244)			Subunit, virosome.	Liquid, prefilled syringe.	Freeze sensitive; store 2–8°C.	Probably SC/IM.	<ul style="list-style-type: none"> Compatibility with stabilization technologies difficult to predict due to varying amounts of lipid in split/subunit formulations. 			
Afluria/Enzira/Fluvax (CSL; V245)			Split.	Liquid, 10-dose vial or prefilled syringe.		IM.	<ul style="list-style-type: none"> Presence of adjuvants (MF59/virosomes) is likely to be incompatible with PATH freeze-prevention technology. Spray-drying (or similar) likely to be possible with 			

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Availability: 2008 2015 2025			Formulation	Existing/2008: Presentation Storage Route			Notes on potential presentation and delivery	
Flulaval (GSK; V247)			Split.	Liquid, 10-dose vial.		IM.	non-live, non-adjuvanted formulations.	
Flumist (MedImmune; V248)			Live attenuated.	Liquid, 1-dose prefilled nasal spray.		IN.		
Optaflu (Novartis; V249)			Subunit.	Probably liquid, prefilled syringe.		IM.		
Agrippal/Begrivac (Novartis; V250)			Subunit.	Liquid, prefilled syringe.		Probably SC/IM.		
Fluad (Novartis; V251)			Subunit, with MF59 adjuvant.	Liquid.	Probably freeze sensitive; store 2–8°C	Probably SC/IM.		
Fluvirin (Novartis; V252)			Split.	Liquid; 10-dose vial, possibly also prefilled syringe.	Freeze sensitive; store 2–8°C.	IM.		
Fluzone and Vaxigrip (Sanofi; V253)				Liquid; 1-, 10-dose vial or prefilled syringe (no 1-dose vial with Vaxigrip).		IM for Fluzone; SC/IM for Vaxigrip.		
Influvac (Solvay; V254)			Subunit.	Liquid.	Probably freeze sensitive; store 2–8°C.			
Invivac (Solvay; V255)			Purified neuraminidase + HA in virosomes.	Liquid, prefilled syringe.	Probably freeze sensitive; store 2–8°C.			
	“Vero cell” (Baxter; V256)		Split.	Probably liquid.	Probably freeze sensitive; store 2–8°C.			
	Flublok (Protein Sciences; V257)		Recombinant HA and neuraminidase.	Unknown.	Unknown.	Probably SC/IM.		
	“ISCOMATRIX” (CSL; V258)		Probably split, with ISCOMATRIX adjuvant.					
	“GSK adjuvant” (GSK; V259)		Probably split, with GSK adjuvant.					
	“ID microinject”		Split.			ID.		

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2008	Availability:		Formulation	Existing/2008:			Notes on potential presentation and delivery
	2015	2025		Presentation	Storage	Route	
	(Sanofi; V260)		Probably split.	Probably liquid, 10-dose vial or prefilled syringe.	Probably freeze sensitive; store 2–8°C.	Probably SC/IM.	
	“Per.C6” (Sanofi; V261)						
		“Alphavirus” (Alphavax; V262)	Live alphavirus vector.	Unknown.	Unknown.		
		Envac (Green Hills; V263)	Live attenuated.			Probably IN.	
		“IC31” (Intercell; V264)	Probably split, with IC31 adjuvant.			Probably SC/IM.	
		“+ IS patch” (Iomai; V265)	Probably split vaccine with IS patch nearby.				
		M2e universal (Vaxxinate; V266)	Recombinant protein with flagellin.				
		“MDCK” (Nobilon; V267)	Probably split.				
JE (VT018)							
JE-VAX (Biken/Sanofi; V005)			Killed virus (from mouse brain).	Lyophilized or liquid.	Freeze sensitive; store 2–8°C.	SC.	<ul style="list-style-type: none"> Mouse-brain-derived vaccines being replaced by vaccines produced in cell culture. PATH freeze-prevention technology not applicable for lyophilized formulations. Not known whether it will be suitable for whole killed virus formulations. Intercell vaccine (IC51™) approved by the European Medicines Agency in 2009. Now designated Ixiaro®.
Japanese encephalitis—live/SA 14-14-2 attenuated (China National; V006)			Live attenuated.	Lyophilized, 1- or 5-dose vial.	Vaccine not freeze sensitive; diluent is; store 2–8°C.		
JE VACCINE (Vabiotech; V010)			Killed virus (from mouse brain).	Lyophilized, 1-dose vial.	Freeze sensitive; store 2–8°C.		
	IC51™ (Intercell; V007)	Killed + Al adjuvant.	Liquid, multi-dose vial or prefilled syringe.	Unknown.		Probably SC.	
	(Biken; V008)	Killed.	Unknown.				
	ChimeriVax™-JE (Acambis/Bharat/Sanofi; V009)	Live attenuated.	Lyophilized, multi-dose vial.			SC.	
	BK-VJE (Biken; V012)	Killed.	Lyophilized, 1- or multi-dose vial.				

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2008	Availability:		Formulation	Existing/2008:			Notes on potential presentation and delivery		
	2015	2025		Presentation	Storage	Route			
Malaria (VT019)									
	Mosquirix/RTS,S (GSK, PATH-MVI; V102)	Protein, as VLPs + AS01 (MPL-QS-21) adjuvant.	Lyophilized.	Freeze sensitive; probably store 2–8°C.	IM.	<ul style="list-style-type: none"> Several novel adjuvants are being evaluated with candidate malaria vaccines. Suitability for stabilization technologies and administration routes will be dependent on adjuvants used. The “standard shake test” will not work with AS01 adjuvant (Mosquirix); therefore, freeze-detector device would be valuable. 			
	PeviPRO (Pevion; V104)	Protein + virosome.	Unknown.	Unknown.	Store 4°C.				
	PfCP2.9 (Sinobiomed; V106)	Protein + Montanide IAS720 (squalene + oil) adjuvant.		Unknown.					
	MSP1/FMP1 (WRAIR; V107)	Protein + Al or AS02 adjuvant.		Probably IM.					
	MSP3-LSP (Institut Pasteur; V108)	Probably protein + Al or Montanide ISA720 adjuvant.			IM, possibly ID.				
	Prime boost (University of Oxford; V103)	Proteins, DNA or live viral vectors.			IM.				
	AMA1, AMA1-C1 (NIAID; V105)	Various: protein + Montanide ISA720 or Al or AS02A adjuvant.			Probably IM.				
	GMZ2 (Staten Serum; V109)	Protein + Al adjuvant.			IM.				
	MSP-2 (LaTrobe, GroPep; V110)	Probably protein + Montanide ISA720 adjuvant.			Probably IM.				
	AdVac® (Crucell; V111)	Live recombinant adenovirus (Ad35).	Liquid.	Unknown.	IM.				
	NMRC-M3V- Ad-PfCA (GenVec; V112)	Live recombinant adenovirus (Ad5).	Probably liquid.		IM.				
	PfAMA-1- FVO (BPRC; V113)	Probably protein.	Unknown.		Probably IM.				

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2008	Availability:		Formulation	Existing/2008:			Notes on potential presentation and delivery		
	2015	2025		Presentation	Storage	Route			
	EBA-175 RII-NG (NIAID; V115)	Protein + Al adjuvant.							
Measles (VT020)									
Measles PQ (Bio Farma; V155)			Live attenuated.	Lyophilized, 10- or 20-dose vial.	Store 2–8°C (diluent must not be frozen).	SC/IM.	<ul style="list-style-type: none"> The lyophilized formulations have the potential to be delivered by aerosol/inhalation following reconstitution. Dry-powder thermostable formulations may be feasible, but possibly technically difficult to develop. Use of reconstitution devices could be advantageous. Aktiv-Dry and PATH have been evaluating spray-drying of measles vaccine (Serum Institute of India). WHO Measles Aerosol Project is evaluating alternatives to the “Classic Mexican Device.” 		
				Unknown.	Unknown.	Unknown.			
				Lyophilized, 1- or 10-dose vial.	Store 2–8°C (diluent can be at room temperature).	SC.			
				Lyophilized, 1-dose vial.	Store 2–8°C (diluent must not be frozen).				
					Store 2–8°C (diluent can be at room temperature).				
				Lyophilized, 1-, 5-, or 10-dose vial.		Unknown.			
				Lyophilized.	Store 2–8°C.	SC.			
				Liquid, the “Classic Mexican Device” (aerosol).	Unknown.	Intra-pulmonary.			
MenA (VT021)									
MenA PS (Beijing; V116)			PS.	Unknown.	Unknown.	Unknown.	<ul style="list-style-type: none"> Not known whether PATH freeze-prevention technology will be compatible with PS vaccines. PsA-TT development is being led by MVP. MVP and PATH evaluated spray-drying of PsA-TT (Serum Institute of India). ID delivery may be possible. 		
	PsA-TT (Serum Institute of India, PATH-MVP; V115)		PS conj. to tetanus + Al adjuvant.	Lyophilized, 10-dose vial.	Freeze sensitive; store 2–8°C.	SC/IM.			

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Availability:			Existing/2008:				Notes on potential presentation and delivery		
2008	2015	2025	Formulation	Presentation	Storage	Route			
MenB (VT021)									
MeNZB (Novartis; V119) Only for NZ			Purified outer membrane vesicles + Al adjuvant.	Unknown.	Unknown.	Probably IM.	• Suitability for stabilization approaches not known due to outer membrane vesicle component.		
						IM.			
						Unknown.			
MenC (VT021)									
Menjugate (Novartis; V120)			PS conj. to CRM197 + Al adjuvant.	Lyophilized; 1-, 5-, or 10-dose pack.	Freeze sensitive; store 2–8°C.	IM.	• Not known whether PATH freeze-prevention technology will be compatible with PS vaccines. • ID delivery may be possible.		
Meningitec (Wyeth; V121)			PS conj. to diphtheria + Al adjuvant.	Liquid.	Unknown.	Probably IM.			
NeisVac-C (Baxter; V160)			PS conj. to tetanus + Al adjuvant.	Liquid, prefilled syringe.	Freeze sensitive; store 2–8°C.	IM.			
		MenC/P64k (Havana; V122)	PS conj. to p64k.	Unknown.	Unknown.	Unknown.			
MenAC (VT021)									
ACVax PQ (GSK; V123)			PS.	Lyophilized; 1-, 10-, 20-, or 50-dose vial.	Unknown.	IM.	• Not known whether PATH freeze-prevention technology will be compatible with PS vaccines. • ID delivery may be possible.		
Meningitis A and C PQ (Biomanguinhos; V124)						Unknown.			
Mengivac PQ (Sanofi; V125)				Lyophilized, 10-dose vial.					
MenAC PS (Intervax; V126)				Lyophilized, 1-dose vial.					
Group A+C Meningococcal Polysaccharide vaccine (China National; V128)				Lyophilized; 1-, 10-, 20-, or 50-dose vial.	Store 2–8°C.	SC.			
		MenAC (China National; V127)	PS conj. to “something.”	Unknown.	Unknown.	Unknown.			
MenBC (VT021)									
VA-MENGOC-B (Finlay; V129)			Purified outer membrane vesicles + PS + Al adjuvant.	Lyophilized.	Unknown.	Unknown.	• Suitability for stabilization approaches not known due to outer membrane vesicle component.		

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Availability:			Existing/2008:				Notes on potential presentation and delivery		
2008	2015	2025	Formulation	Presentation	Storage	Route			
MenACW135Y (VT021)									
Mencevax ACWY (GSK; V130)			PS.	Lyophilized; 1- or 10-dose vial or prefilled syringe.	Store 2–8°C.	Unknown.	<ul style="list-style-type: none"> Not known whether PATH freeze-prevention technology will be compatible with PS vaccines. ID delivery may be possible. 		
Menactra (Sanofi; V133)			PS conj. to diphtheria.	Liquid, 1-dose vial.		IM.			
Menomune®-A/C/Y/W-135 (Sanofi; V198)			PS, not conj.	Lyophilized; 1- or 10-dose vial.		SC.			
	Menveo (Novartis; V131)		PS conj. to diphtheria.	Unknown.	Unknown.	Unknown.			
MenACW135 (VT021)									
Mencevax ACW PQ (GSK; V132)			PS.	Lyophilized, multi-dose vial.	Store 2–8°C.	SC/IM.	<ul style="list-style-type: none"> Not known whether PATH freeze-prevention technology will be compatible with PS vaccines. 		
Pneumo (VT022)									
Prevnar (Wyeth; V149)			7-valent, conj. to diphtheria + Al adjuvant.	Liquid, 1-dose vial or prefilled syringe.	Freeze sensitive; store 2–8°C.	IM.	<ul style="list-style-type: none"> Not known whether PATH freeze-prevention technology will be compatible with PS vaccines. ID delivery may be possible. 		
Pneumovax II, Pneumo 23 (Sanofi; V152)			23-valent, unconj.			IM.			
Pneumovax 23 (Merck; V153)			23-valent, unconj.	Liquid, 1- or 5-dose vial.	Store 2–8°C.	Unknown.	<ul style="list-style-type: none"> Not known whether PATH freeze-prevention technology will be compatible with PS vaccines. ID delivery may be possible. 		
Ronsen® (China National; V154)			23-valent, unconj	Unknown.		SC/IM.			
	13vPnC (Wyeth; V150) Expected 2009		13-valent, conj. to diphtheria.	Probably liquid, 1-dose vial or prefilled syringe.	Freeze sensitive; store 2–8°C.	Probably IM.	<ul style="list-style-type: none"> Not known whether PATH freeze-prevention technology will be compatible with PS vaccines. ID delivery may be possible. 		
	Synflorix (GSK; V151) Expected 2008		10-valent, conj. to non-typeable Hib protein D, Al adjuvant.	Liquid, 1- or 2-dose vial or prefilled syringe.					
Polio—OPV (VT023)									
Polio 20 doses PQ (Bio Farma; V215)			3-valent live attenuated.	Liquid, 10- or 20-dose vial.	Frozen, then store 2–8°C.	Oral.	<ul style="list-style-type: none"> PATH freeze-prevention technology not applicable. Oral delivery route unlikely to change before use of OPV ceases. 		
PQ (Sanofi; V216)				Probably liquid, multi-dose vial.					
Polioral PQ (Novartis; V217)				Probably frozen, then store 2–8°C.					
PV PQ (GSK; V218)				Liquid; 1-, 10-, or 25-dose vial.	Store 2–8°C				
Poliomyelitis vaccine (oral) IP PQ (Haffkine; V219)				Liquid, 20-dose vial.	Frozen, then store 2–8°C.				
Poliomyelitis vaccine, live (oral) IP PQ									

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Availability: 2008	2015	2025	Formulation	Presentation	Storage	Route	Notes on potential presentation and delivery	
(Panacea; V220)								
(Birmex; V221)				As candy pill, 10 per bag.	Frozen, then store 2–8°C.			
OPV (China National; V222)				Probably liquid, multi-dose vial.	Frozen, then store 2–8°C.			
(Bio Manguinhos; V223)				Liquid, 20-dose vial.				
BIOPOLIO (Bharat; V224)								
Polio—mOPV1 (VT023) + 2 others								
mOPV1 PQ (Sanofi; V229)			1-valent live attenuated.	Unknown.	Unknown.	Oral.	<ul style="list-style-type: none"> PATH freeze-prevention technology not applicable. Oral delivery route unlikely to change before use of OPV ceases. 	
mOPV1 (GSK; V310)				Liquid, 10- or 20-dose vial.	Store 2–8°C.			
mOPV1 (Panacea; V230)				Unknown.	Unknown.			
Polio—mOPV3 (VT023) + 2 others								
mOPV3 (Panacea; V231)			1-valent live attenuated.	Unknown.	Unknown.	Oral.	<ul style="list-style-type: none"> As for mOPV1. 	
mOPV3 (GSK; V311)				Liquid, 10- or 20-dose vial.	Store 2–8°C.			
Polio—IPV (VT023)								
IPOL PQ (Sanofi; V225)			3-valent killed.	Liquid, 10-dose vial or prefilled syringe.	Freeze sensitive; store 2–8°C.	SC/IM.	<ul style="list-style-type: none"> PATH freeze-prevention technology or spray-drying likely to be applicable. ID delivery may be possible and could be advantageous due to cost and manufacturing capacity for IPV. 	
(Panacea; V226)				Probably liquid.	Unknown.	Probably SC/IM.		
(SBL Vaccin; V227)				Liquid, 1-dose vial or prefilled syringe.				
Poliorix (GSK; V309)				Liquid; 1-, 2-, or 10-dose vial.	Store 2–8°C.	IM.		
IPV-Virelon (Novartis; V228)				Probably liquid.	Unknown.	Probably SC/IM.		
	Sabin-IPV (JPRI, Bio Farma; V232)	3-valent from Sabin attenuated strains, killed.		Unknown.	Unknown.			
Rabies (VT025)								
Rabipur/RabAvert/Rabivac PQ (Novartis; V067)			Killed virus.	Lyophilized, 1-dose vial.	Not freeze sensitive; store 2–8°C.	IM or ID.	<ul style="list-style-type: none"> Reconstitution devices could be advantageous for lyophilized formulations (although might increase costs and waste volume). PATH project to evaluate ID delivery devices will use rabies vaccine (Indian Immunologicals). Spray-drying may be possible as an alternative to lyophilization. 	
IMOVAX®/Verorab PQ (Sanofi; V068)				Freeze sensitive; store 2–8°C.	IM; ID in some countries.	IM.		
Sii Rabivax (Serum Institute of India; V069)				Liquid, 1-dose vial.				

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Availability: 2008 2015 2025			Existing/2008: Formulation Presentation Storage Route				Notes on potential presentation and delivery				
(Japan; V070)			Lyophilized, 1-dose vial. Lyophilized and also liquid. Lyophilized or liquid, concentrated or not. Lyophilized, prefilled syringe. Lyophilized, 1-dose vial.	Lyophilized, 1-dose vial. Lyophilized and also liquid. Lyophilized or liquid, concentrated or not. Lyophilized, prefilled syringe. Lyophilized, 1-dose vial.	Freeze sensitive, store 2–8°C. Store 2–8°C. Unknown.	Deep IM. IM.	<ul style="list-style-type: none"> Repackaging to reduce space required in cold chain and/or use of reconstitution device would be advantageous. Diluent for Rotarix can be stored at room temperature and cooled before reconstitution. Aridis/PATH working on thermostable formulations. 				
Abhayrab (Indian Immunologicals; V071)											
Wusheng® (China National; V072)											
Cocav™ Vnukovo-32 primary hamster kidney cell vaccine for humans (Russia; V073)											
Lyssavac N™/Vaxirab™ PQ purified duck embryo rabies vaccine (Zydus Cadila; V074)											
INDIRAB® (Bharat; V075)											
Rotavirus (VT026)											
Rotarix PQ (GSK; V138)			1-valent live attenuated.	Lyophilized + adaptor + oral dosing; 1-dose; packs of 1, 5, 10, and 25; also new liquid formulation.	Store 2–8°C.	Oral.	<ul style="list-style-type: none"> Repackaging to reduce space required in cold chain and/or use of reconstitution device would be advantageous. Diluent for Rotarix can be stored at room temperature and cooled before reconstitution. Aridis/PATH working on thermostable formulations. 				
Rotateq PQ (Merck; V140)			5-valent live attenuated.	Liquid in squeeze tube; 1-dose; packs of 10.	Store 2–8°C.						
	Human-bovine reassortment (Aridis, China National, Shantha, PATH; V139)		4-valent live attenuated.	Unknown.	Unknown.						
	RV3 (Bio Farma/Murdoch, Q-Gen; V142)		1-valent live attenuated.								
	116E (Bharat, PATH; V141)			Liquid in glass.	Stored frozen for trial.						
RSV (VT024)											
	F, G, and M (Sanofi; V065)		Proteins.	Unknown.	Unknown.	Unknown.	<ul style="list-style-type: none"> Not enough information on formulations to comment on stability/presentation. 				
		MEDI-534 (MedImmune; V064)	Live attenuated.			IN.					
						Unknown.					
Shigella (VT027)											
[FS]			2-valent live	Unknown.	Unknown.	Unknown.	▪ FS (Lanzhou)—recently canceled.				

Landscape analysis: trends in vaccine availability and vaccine delivery technologies
 Summary tables of vaccine types and individual vaccines (licensed and in clinical phase of development)

ANNEX 1

Availability:			Existing/2008:				Notes on potential presentation and delivery
2008	2015	2025	Formulation	Presentation	Storage	Route	
Shigella (VT027)							
[FS (Lanzhou; V043)]			2-valent live attenuated.	Unknown.	Unknown.	Unknown.	• FS (Lanzhou)—recently canceled. • Not enough information on formulations to comment on stability/presentation.
	SC602 (Institut Pasteur; V044)		Live attenuated.			Oral.	
	SC599 (Institut Pasteur; V045)					Injected.	
	Prototype parenteral conjugate vaccine (NICHD; V048)		LPS conj. to rEPA protein.				
	WRSS1 (WRAIR; V046)		Live attenuated.			Oral.	• All formulations likely to be compatible with PATH freeze-protection technology or spray-drying. • ID delivery may be possible depending on adjuvant reactogenicity.
	CVD 1208 (University of Maryland; V047)						
	SsWC (Johns Hopkins; V049)		Killed bacteria.				
	Invaplex 50 (Johns Hopkins; V050)		Protein LPS.			IN.	
	Proteosome-Shigella flexneri 2a LPS vaccine (Intellivax; V051)		Killed bacteria complexed to outer membrane proteins and proteosomes.				
TT (VT028)							
Tetatox PQ (BB-NCIPD; V177)	Toxoid + Al adjuvant.		Liquid; 1-, 10-, or 20-dose vial.	Freeze sensitive; store 2–8°C.	IM.	IM.	• All formulations likely to be compatible with PATH freeze-protection technology or spray-drying. • ID delivery may be possible depending on adjuvant reactogenicity.
TT PQ (Bio Farma; PATH; V178)			Liquid; 10- or 20-dose vial or Uniject™ device.		SC/IM.		
TT PQ (Sanofi; V179)			Liquid, 1-dose vial.				
Anatoxal Te PQ (Berna; V180)			Liquid; 1-, 2-, 10-, or 50-dose vial.				
PQ (Serum Institute of India; V181)			Liquid, 1-dose ampoule or 10-				

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ANNEX 1

Availability: 2008 2015 2025			Formulation	Existing/2008: Presentation Storage Route			Notes on potential presentation and delivery	
PQ (Shantha; V182)			Probably toxoid + Al adjuvant.	dose vial.				
(China National; V183)				Probably liquid.	Probably freeze sensitive; store 2–8°C.	Probably SC/IM.		
Vax-Tet (Finlay; V184)								
TE-VAC (Bharat; V185)			Toxoid + Al adjuvant.	Probably liquid, 10-dose vial.	Freeze sensitive; store 2–8°C	Probably SC/IM.		
(Intervax; V186)			Toxoid + probably Al adjuvant.	Liquid; 1-, 5-, or 10-dose vial.	Probably freeze sensitive; store 2–8°C	Probably SC/IM.		
(Haffkine; V187)				Liquid, 10-dose vial.		IM.		
Tetanol and Tetanol-pur (Novartis; V188)			Toxoid + Al adjuvant.	Probably liquid.		Probably SC/IM.		
TB (VT029)								
Tuvax PQ (Japan BCG; V200)			Live attenuated.	Lyophilized, vial + diluent.	Antigen not freeze sensitive; store 2–8°C. Protect from light.	ID.	<ul style="list-style-type: none"> • Might be possible to develop spray-dried live BCG formulations for aerosol delivery (David Edwards, Massachusetts Institute of Technology). • PATH freeze-prevention technology not applicable to the lyophilized formulations, and suitability will be dependent on which adjuvant is present in the killed formulations. 	
BCG PQ (BB-NCIPD/Intervax; V201)				Lyophilized, 10- or 20-dose vial + diluent.				
BCG-vaccine-SSI PQ (Staten Serum; V202)				Lyophilized, 1-dose vial + diluent.				
BCG PQ (Serum Institute of India; V203)				Lyophilized, 10- or 20-dose vial + diluent.				
BCG (Bio Farma; V04)				Lyophilized, multi-dose vial + diluent.	Store 2–8°C or freeze; protect from light.			
(Sanofi; V205)				Lyophilized, multi-dose vial + diluent.	Do not freeze; store 2–8°C; protect from light.			
	SSI Hyvac4 (Aeras-404) (SSI, Intercell, Aeras, Sanofi; V207)		Protein + IC31 adjuvant.	Unknown.	Unknown.	Probably injected.		
	GSK M72 (GSK, Aeras; V208)		Protein + AS01 adjuvant.					
	MVA-85[®]/Aeras-485 (University of Oxford, Aeras; V209)		Live vaccinia.					
	SSI Hybrid 1 (SSI, TBVI, Intercell; V210)		Protein + IC31 adjuvant.	Liquid or lyophilized.	Unknown.			
	Aeras 402 (Aeras, Crucell; V211)		Live adenovirus.					

2008	Availability:		Formulation	Existing/2008:			Notes on potential presentation and delivery		
	2015	2025		Presentation	Storage	Route			
	rBCG30 (UCLA, Aeras; V212)		Recombinant BCG (mycobacteria).			Probably ID.			
	<i>Mycobacterium vaccae</i> (SR Pharma; V213)		Killed mycobacteria.			Probably injected.			
	RUTI (Barcelona; V214)		Fragmented Mycobacterium Tb.						
Typhoid (VT030)									
Typherix (GSK; V017)			PS.	Liquid, 1-dose prefilled syringe.		IM.	<ul style="list-style-type: none"> PS vaccines may not be suitable for PATH freeze-prevention technology. Sugar-glass stabilization (spray-drying) has been demonstrated with Ty800. Possibly suitable for PATH freeze-prevention technology. 		
Vivotif (Berna; V018)			Live attenuated.	Either sachet of lyophilized + sachet of buffer (with water) or enteric coated capsule (for > 5 yo).	Store 2–8°C.	Oral.			
Typhim Vi (Sanofi; V019)			PS.	Liquid, 1-dose prefilled syringe or 10- or 20-dose vial.	Store 2–8°C.	SC/IM.			
Typhoral (Novartis; V020)			Live attenuated.	Gelatin capsule.		Oral.			
Typhoid Vi PS (China National; V147)			PS.	Liquid.	Store 2–8°C	IM.			
	Ty800 (Avant; V023)		Live attenuated.	Capsule.		Oral.	<ul style="list-style-type: none"> PS vaccines may not be suitable for PATH freeze-prevention technology. Sugar-glass stabilization (spray-drying) has been demonstrated with Ty800. Possibly suitable for PATH freeze-prevention technology. 		
	Prototype conj. Vi (NICHD; V024)		PS conj. to rEPA.	Liquid.		Probably injected.			
	(Shantha; V025) Expected 2010		PS.	Unknown.		Oral.			
	(Biopharma; V026) Expected 2010		PS.			Injectable.			
	CVD 909 (University of Maryland; V028)		Live attenuated.			Oral.			
	Vi-DT conjugate (NIH +; V029) Expected 2014		PS conj. to diphtheria.			Oral.			
	(Borjung; V021)		Live attenuated.			Oral.			
ZH9 (Emergent; V022)				Capsule.		Oral.			

Landscape analysis: trends in vaccine availability and vaccine delivery technologies
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ANNEX 1

Availability:			Existing/2008:				Notes on potential presentation and delivery	
2008	2015	2025	Formulation	Presentation	Storage	Route		
	Expect 2013							
	Typbar-Vi (Bharat; V027)	PS unknown.	Glass vial, 1- or multi-dose.			IM.		
VZV (VT031)								
Varivax (Sanofi/Merck; V059)			Live attenuated.	Lyophilized + diluent; 1- or multi-dose; vial or prefilled.	Not freeze sensitive; store 2-8°C.	SC.	• Reconstitution devices could be advantageous.	
Varilrix® (GSK; V060)				Lyophilized + diluent.	Store 2-8°C.			
(Green Cross; V061)				Lyophilized.	Stored frozen.			
Zostavax (Merck; V062)				Unknown.	Unknown.	Unknown.		
Okavax (Biken; V137)				Lyophilized + diluent.	Store 2-8°C or -10°C (lyophilized powder only)	Probably SC.		
Live attenuated VZV (China National; V145)				Lyophilized + diluent, 1-dose vial.	Store 2-8°C, preferably frozen during transport.	SC.		
	Varicella Vaccine (Tiantan Strain) (China National; V148)		Unknown.	Unknown.	Unknown.	Unknown.	• Used in WHO stockpile. • Suitability for spray-drying not known. • Reconstitution device could be advantageous.	
		(University of Colorado; V136)	Killed virus.			SC.		
YF (VT032)								
Stamaril PQ (Sanofi; V030)			Live attenuated.	Lyophilized; 1-, 5-, 10-, or 20-dose vial + diluent.	Not freeze sensitive; store 2-8°C.	Deep SC/IM.	• Used in WHO stockpile. • Suitability for spray-drying not known. • Reconstitution device could be advantageous.	
YF vaccine PQ (Bio-Manguinhos; V032)					Freeze sensitive; store 2-8°C.			
YF vaccine PQ (Institut Pasteur Dakar; V033)					Unknown.			
YF-Vax (Sanofi; V031)						Unknown.		
Arilvax® (Novartis, Acambis; V034)				Unknown.		Deep SC/IM.		

Sources

List of manufacturers surveyed: search of website for products and also pipeline (clinical/preclinical)

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Also:

- Aeras Global TB Vaccine Foundation; European Medicines Agency; US Food and Drug Administration; International Federation of Pharmaceutical Manufacturers and Associations (IFPMA); PATH; WHO.

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